

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
NEWARK DIVISION**

TERESA GUSTIN and PAMELA GUSTIN,
Individually, and as Trustees of THE
GUSTIN FAMILY TRUST,

Plaintiffs,

v.

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

No. _____

**DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S
ANSWER AND JURY DEMAND**

Pursuant to Rule 12 of the Federal Rules of Civil Procedure, Defendant Novartis Pharmaceuticals Corporation (“NPC”), by and through its counsel, respectfully responds by generally denying all allegations in the Complaint and Jury Demand (“the Complaint”) of plaintiffs Teresa Gustin and Pamela Gustin, individually and as Trustees of the Gustin Family Trust, except as set forth below. Silence as to any allegations shall constitute a denial:

1. The allegations in Paragraph 1 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 1 of the Complaint.

2. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint and therefore denies the same. NPC specifically denies that any injuries alleged in the Complaint were caused by Tassigna[®].

3. NPC denies that any injuries alleged in the Complaint were caused by Tassigna[®] and denies that the plaintiffs are entitled to any of the relief sought.

JURISDICTION AND VENUE

4. NPC denies the allegations in Paragraph 4 of the Complaint.

5. NPC admits that NPC is a Delaware corporation with its principle place of business located in East Hanover, New Jersey. The remaining allegations in Paragraph 5 constitute legal conclusions to which no response is required. To the extent that a response is deemed required, NPC denies the allegations in Paragraph 5.

6. The first two sentences of Paragraph 6 comprise attorney characterizations and are accordingly denied. NPC admits that it engaged in marketing activities in New Jersey for Tassigna[®]. The remaining allegations in Paragraph 6 constitute legal conclusions to which no response is required. To the extent that a response is deemed required, NPC denies the remaining allegations in Paragraph 6.

7. The allegations in paragraph 7 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 7.

THE PARTIES

The Plaintiffs

8. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 8 of the Complaint and therefore denies the same.

9. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 9 of the Complaint and therefore denies the same.

10. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 10 of the Complaint and therefore denies the same.

11. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 11 of the Complaint and therefore denies the same.

The Defendant

12. NPC admits that it is a Delaware corporation with its principle place of business located in East Hanover, New Jersey. NPC admits that it researches, develops, markets, and sells the cancer medicine bearing the name Tasigna[®], as well as numerous other medications. NPC denies the remaining allegations in Paragraph 12 of the Complaint.

GENERAL ALLEGATIONS

13. The allegations in paragraph 13 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 13.

14. The allegations in paragraph 14 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 14.

15. The allegations in paragraph 15 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 15.

16. The allegations in paragraph 16 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 16.

17. The allegations in paragraph 17 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 17.

18. The allegations in paragraph 18 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 18.

19. The allegations in paragraph 19 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 19.

20. The allegations in paragraph 20 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 20.

21. The allegations in paragraph 21 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 21.

22. The allegations in paragraph 22 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 22.

23. NPC admits that Tasigna[®] is a cancer medication that is FDA-approved to treat patients with Philadelphia chromosome positive chronic myeloid leukemia (“Ph+CML”). NPC affirmatively avers that chronic myeloid leukemia is a cancer that occurs when the blood-forming cells of the bone marrow make too many white blood cells, including immature ones. PH+CML is caused by a genetic abnormality that produces an abnormal chromosome in bone

marrow stem cells – the Philadelphia chromosome (abbreviated ‘Ph chromosome’ or simply ‘Ph’). The Ph chromosome carries a gene called BCR-ABL, which produces a protein called Bcr-Abl. The Bcr-Abl protein triggers bone marrow to keep making abnormal versions of white blood cells, which are the leukemia cells. The BCR-ABL gene and Bcr-Abl protein are the key causes of Ph+CML. The resulting uncontrolled growth of these white blood cells will cause a large increase in their concentration in the blood. Over time, these white blood cells crowd out healthy red blood cells and platelets as well as normal white cells. Tasigna® is an inhibitor of the BCR-ABL Kinase. Tasigna® is considered a tyrosine kinase inhibitor (“TKI” medicine). NPC denies all allegations of Paragraph 23 of the complaint that are inconsistent with its affirmative averment above.

24. NPC admits that Gleevec® was first FDA approved in 2001 and that it is a drug that was and is distributed by NPC in the United States. The remaining allegations contained in Paragraph 24 of the Complaint are impertinent and immaterial as the allegations do not allege that any injuries resulted from Gleevec® treatment. Moreover, the allegations are vague in that they do not identify the payer in their hypothetical allegations regarding “cost.” NPC admits that the list price of Gleevec® pills has increased in the fifteen years since market introduction in 2001 by about threefold. NPC admits that the Wholesale Acquisition Cost for twelve months of Gleevec® treatments for CML, if a patient is fully compliant, has at times been more than \$100,000. NPC lacks knowledge and information regarding what Gleevec® “costs” any particular patient. NPC denies the remaining allegations contained in Paragraph 24 as they relate to NPC.

25. NPC admits that, as of July 4, 2015 the basic compound patent for Gleevec® in the United States was no longer in effect. NPC denies that “there are currently several generic

forms of Gleevec® on the market.” NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the last clause in Paragraph 25 of the Complaint and therefore denies the same. NPC denies any remaining allegations in Paragraph 25 of the Complaint.

26. NPC admits that it was involved in the development of the cancer medicine Tasigna®. NPC admits that the quoted language contained in Paragraph 26 has been reported, but cannot confirm the accuracy of the quotation. NPC affirmatively avers that the quotation is presented in a misleading way in Paragraph 26. NPC denies the remaining allegations in Paragraph 26 of the Complaint.

27. NPC denies the allegations in Paragraph 27 of the Complaint. Answering further, to the extent the allegations in Paragraph 27 refer to extrinsic documents not attached to or part of this Complaint, NPC states that such documents speak for themselves. NPC denies the allegations to the extent they misstate or mischaracterize such documents.

28. NPC denies the allegations in Paragraph 28 of the Complaint. Answering further, to the extent the allegations in Paragraph 28 refer to extrinsic documents not attached to or part of this Complaint, NPC states that such documents speak for themselves. NPC denies the allegations to the extent they misstate or mischaracterize such documents.

29. NPC admits that it received a letter dated July 29, 2010 from the FDA that requested that NPC remove certain content then on the Tasigna® website. NPC admits that the language contained in quotations in Paragraph 29 appears in that letter, but affirmatively avers that the quotations are presented in a misleading way in Paragraph 29. NPC otherwise denies the allegations in Paragraph 29 of the Complaint.

30. NPC denies the allegations of Paragraph 30 of the Complaint.

31. The allegations contained in Paragraph 31 relate to conduct that allegedly occurred in Japan. NPC, which does not operate in Japan, lacks knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 31 and, therefore, denies the same.

32. NPC denies the allegations contained in Paragraph 32 of the Complaint.

33. NPC admits that it identified a weak safety signal of peripheral arterial occlusive disease (“PAOD”) in Tasigna[®] users and that NPC disclosed this to the FDA in March 2011. NPC sought and FDA approved of the addition of PAOD to Tasigna[®]’s US package insert in November 2011. NPC denies the remaining allegations contained in Paragraph 33 of the Complaint.

34. NPC denies the allegations in Paragraph 34 of the Complaint. Answering further, to the extent that the allegations in Paragraph 34 refer to documents not attached to or part of this Complaint, NPC states that such documents speak for themselves. NPC denies the allegations to the extent they misstate or mischaracterize such documents.

35. NPC denies the allegations contained in Paragraph 35 of the Complaint. Answering further, to the extent that the allegations in Paragraph 35 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

36. NPC denies the allegations in the first sentence of Paragraph 36 of the Complaint. NPC does not operate in Canada and, therefore, denies that these actions are attributable to NPC. Answering further, to the extent that the allegations in Paragraph 36 refer to documents not attached to or part of this Complaint, NPC states that such documents speak for themselves. NPC denies the allegations to the extent they misstate or mischaracterize such documents

37. On April 12, 2013, Novartis Pharmaceuticals Canada, Inc., sent a letter to Canadian health care providers regarding “Updated information regarding the possible risk of developing atherosclerosis-related conditions with the use of Tasigna® (nilotinib).” NPC admits that it did not send a similar letter to health care providers in the United States on April 12, 2013. NPC denies any remaining allegations in Paragraph 37 of the Complaint. NPC does not operate in Canada and, therefore, denies that these actions are attributable to NPC. NPC denies any allegations contained in Paragraph 37 that are inconsistent with the statements set forth in response to that paragraph above.

38. NPC denies the allegations contained in Paragraph 38 of the Complaint.

39. NPC denies the allegations contained in Paragraph 39 of the Complaint.

40. NPC denies the allegations contained in Paragraph 40 of the Complaint.

41. NPC denies the allegations in the first sentence of Paragraph 41. The remaining allegations in Paragraph 41 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is required, NPC denies the allegations.

42. NPC denies the allegations contained in Paragraph 42 of the Complaint. Answering further, to the extent that the allegations in Paragraph 42 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

43. NPC denies the allegations contained in Paragraph 43 of the Complaint. Answering further, to the extent that the allegations in Paragraph 43 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

44. NPC denies the allegations contained in Paragraph 44 of the Complaint.

Answering further, to the extent that the allegations in Paragraph 44 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

45. NPC denies the allegations contained in Paragraph 45 of the Complaint.

46. NPC denies the allegations contained in Paragraph 46 of the Complaint.

47. NPC denies the allegations contained in Paragraph 47 of the Complaint.

Answering further, to the extent that the allegations in Paragraph 47 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

48. NPC denies the allegations contained in Paragraph 48 of the Complaint.

Answering further, to the extent that the allegations in Paragraph 48 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

49. NPC denies the allegations contained in Paragraph 49 of the Complaint.

Answering further, to the extent that the allegations in Paragraph 49 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

50. NPC denies the allegations contained in Paragraph 50 of the Complaint.

51. NPC denies the allegations contained in Paragraph 51 of the Complaint

52. NPC denies the allegations contained in Paragraph 52 of the Complaint.

53. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 53 of the Complaint and therefore denies the same. NPC denies that Tassigna[®]'s FDA-approved labeling is or was ever inadequate.

54. NPC denies the allegations contained in Paragraph 54 of the Complaint

55. NPC denies that plaintiff-decedent's injuries were caused by Tassigna[®]. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 55 and therefore denies the same.

56. NPC denies the allegations contained in Paragraph 56 of the Complaint.

57. NPC denies the allegations contained in Paragraph 57 of the Complaint

58. NPC denies the allegations contained in Paragraph 58 of the Complaint. NPC specifically denies that plaintiffs are entitled to punitive damages in New Jersey. *See* N.J.S.A. § 2A:58C-5(c).

CLAIMS FOR RELIEF

COUNT I: STRICT PRODUCTS LIABILITY

59. In response to Paragraph 59 of the Complaint, NPC incorporates by reference its responses to the allegations in paragraphs 1-58 of the Complaint.

60. NPC admits that it is currently and between 2007 and the present was engaged in selling, marketing, promoting, and distributing Tassigna[®] in the United States. NPC admits that prior to 2007 it was involved in developing the cancer medicine Tassigna[®]. NPC denies all the remaining allegations contained in Paragraph 60 of the Complaint.

61. NPC admits that it is currently and between 2007 and the present was engaged in selling, marketing, promoting, and distributing Tassigna[®] in the United States. The remaining

allegations in Paragraph 61 set forth conclusions of law for which no response is required. To the extent a response is required, NPC denies the allegations in Paragraph 61 of the Complaint.

62. The allegations in Paragraph 62 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 62.

63. NPC denies the allegations contained in Paragraph 63 of the Complaint

64. NPC denies the allegations contained in Paragraph 64 of the Complaint

65. NPC denies the allegations contained in Paragraph 65 of the Complaint

66. NPC denies the allegations contained in Paragraph 66 of the Complaint.

67. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 67 of the Complaint and therefore denies the same.

68. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 68 of the Complaint and therefore denies the same.

69. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 69 of the Complaint and therefore denies the same.

70. NPC denies that there are any defects associated with Tassigna[®]. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 70 of the Complaint and therefore denies the same.

71. NPC denies the allegations contained in Paragraph 71 of the Complaint.

72. NPC denies the allegations contained in Paragraph 72 of the Complaint.

73. The allegations in Paragraph 73 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 73.

74. NPC denies the allegations contained in Paragraph 74 of the Complaint.

75. NPC denies the allegations contained in Paragraph 75 of the Complaint.

76. NPC denies the allegations contained in Paragraph 76 of the Complaint.

77. NPC denies the allegations contained in Paragraph 77 of the Complaint.

78. NPC denies the allegations contained in Paragraph 78 of the Complaint.

In response to the WHEREFORE paragraph following paragraph 78, NPC demands that judgment be entered in its favor and against plaintiffs; that plaintiffs' Complaint be dismissed, with prejudice; and that NPC be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper. NPC specifically denies that plaintiffs are entitled to punitive damages in New Jersey. *See* N.J.S.A. § 2A:58C-5(c).

ASSERTION OF CLAIMS PURSUANT TO THE LAWS OF KENTUCKY

79. In response to Paragraph 79 of the Complaint, NPC incorporates by reference its responses to the allegations in paragraphs 1-78 of the Complaint.

80. NPC denies the allegations contained in Paragraph 80 of the Complaint. To the extent that the allegations in the Complaint constitute legal conclusions, no response is required.

COUNT II: NEGLIGENCE

81. In response to Paragraph 81 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraph 1-80 of the Complaint.

82. NPC admits that it is currently and between 2007 and the present was engaged in selling, marketing, promoting, and distributing Tassigna[®] in the United States. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 82 of the Complaint and therefore denies the same.

83. The allegations in Paragraph 83 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 83 of the Complaint.

84. The allegations in Paragraph 84 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 84 of the Complaint.

85. NPC denies the allegations contained in Paragraph 85 of the Complaint.

86. NPC denies the allegations contained in Paragraph 86 of the Complaint.

87. NPC denies the allegations contained in Paragraph 87 of the Complaint.

88. The allegations in Paragraph 88 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 88 of the Complaint.

89. The allegations in Paragraph 89 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 89 of the Complaint.

90. NPC denies the allegations contained in Paragraph 90 of the Complaint.

91. NPC denies the allegations contained in Paragraph 91 of the Complaint and each of its subparts.

92. NPC denies the allegations contained in Paragraph 92 of the Complaint.

93. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 93 of the Complaint and therefore denies the same.

94. NPC denies the allegations contained in Paragraph 94 of the Complaint.

95. NPC denies the allegations contained in Paragraph 95 of the Complaint.

96. NPC denies the allegations contained in Paragraph 96 of the Complaint.

97. NPC denies the allegations contained in Paragraph 97 of the Complaint.

98. NPC denies the allegations contained in Paragraph 98 of the Complaint.

In response to the WHEREFORE paragraph following paragraph 98, NPC demands that judgment be entered in its favor and against plaintiffs; that plaintiffs' Complaint be dismissed, with prejudice; and that NPC be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper. NPC specifically denies that plaintiffs are entitled to punitive damages in New Jersey. *See* N.J.S.A. § 2A:58C-5(c).

COUNT III: STRICT LIABILITY

99. In response to Paragraph 99 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraphs 1-98 of the Complaint.

100. NPC admits that it is currently and between 2007 and the present was engaged in selling, marketing, promoting, and distributing Tassigna® in the United States. NPC denies the remaining allegations contained in Paragraph 100 of the Complaint.

101. The allegations in Paragraph 101 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 101 of the Complaint.

102. The allegations in Paragraph 102 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 102 of the Complaint.

103. NPC denies the allegations contained in Paragraph 103 of the Complaint.

104. NPC denies the allegations contained in Paragraph 104 of the Complaint.

105. The allegations in Paragraph 105 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 105 of the Complaint.

106. NPC denies the allegations contained in Paragraph 106 of the Complaint.

107. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 107 of the Complaint and therefore denies the same.

108. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 108 of the Complaint and therefore denies the same.

109. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 109 of the Complaint and therefore denies the same.

110. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 110 of the Complaint and therefore denies the same.

111. NPC denies the allegations contained in Paragraph 111 of the Complaint.

112. NPC denies the allegations contained in Paragraph 112 of the Complaint.

113. The allegations in Paragraph 113 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 113 of the Complaint.

114. The allegations in Paragraph 114 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 114 of the Complaint.

115. NPC denies the allegations contained in Paragraph 115 of the Complaint.

116. NPC denies the allegations contained in Paragraph 116 of the Complaint.

117. NPC denies the allegations contained in Paragraph 117 of the Complaint.

118. NPC denies the allegations contained in Paragraph 118 of the Complaint.

In response to the WHEREFORE paragraph following paragraph 118, Defendant demands that judgment be entered in its favor and against plaintiffs; that plaintiffs' Complaint be dismissed, with prejudice; and that Defendants be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper. NPC specifically denies that plaintiffs are entitled to punitive damages in New Jersey. *See* N.J.S.A. § 2A:58C-5(c).

COUNT IV: WRONGFUL DEATH AND SURVIVAL ACTION

119. In response to Paragraph 119 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraphs 1-118 of the Complaint.

120. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 120 of the Complaint and therefore denies the same.

121. NPC admits that plaintiffs purport to bring a claim, but deny any liability to that claim.

122. NPC denies that Plaintiff-Decedent suffered any injury or death due to Tasigna®. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 122 of the Complaint and therefore denies the same.

123. NPC denies the allegations contained in Paragraph 123 of the Complaint.

124. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 124 of the Complaint and therefore denies the same. To the extent that the allegations in Paragraph 124 of the Complaint constitute legal conclusions no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 124 of the Complaint.

In response to the WHEREFORE paragraph following paragraph 124, NPC demands that judgment be entered in its favor and against plaintiffs; that plaintiffs' Complaint be dismissed, with prejudice; and that NPC be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper. NPC specifically denies that plaintiffs are entitled to punitive damages in New Jersey. *See* N.J.S.A. § 2A:58C-5(c).

Every allegation in the Complaint that is not specifically and expressly admitted in this Answer is hereby specifically and expressly denied, including any allegations contained in the headings of Plaintiffs' complaint

AFFIRMATIVE DEFENSES

1. The Complaint, in whole or part, fails to state a claim or cause of action against NPC upon which relief can be granted.
2. Plaintiffs' claims are barred by their failure to join necessary or indispensable parties.
3. The doctrines contained in Restatement (Second) of Torts § 402A, Comment K, bar plaintiffs' claims against NPC in whole or in part.
4. The doctrine(s) contained in Restatement (Third) of Torts, Product Liability §§ 4 and 6, bar plaintiffs' claims against NPC in whole or in part.
5. Applicable statutes of limitations or repose bar plaintiffs' claims in whole or in part. *E.g.*, N.J. Stat. Ann. § 2A:31-3.
6. The equitable doctrine of laches, waiver and/or estoppel bar plaintiffs' claims in whole or in part.

7. Plaintiffs' misuse or abnormal use of the products or failure to follow instructions bar the plaintiffs' claims in whole or in part.

8. The alleged injuries to plaintiffs were proximately caused by the misuse, abuse, alteration, and/or failure to properly utilize, maintain, or care for the products by persons other than NPC.

9. Plaintiffs' claims are barred, in whole or in part, because the decedent assumed the risks disclosed by the product labeling, by the prescribing physicians, or by other persons or entities.

10. Any alleged negligent or culpable conduct of NPC, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of plaintiffs' alleged injuries.

11. To the extent decedent used the product for "off-label" purposes, plaintiffs' claims are barred.

12. The "learned intermediary" doctrine bars plaintiffs' claims.

13. Plaintiffs' claims are barred, in whole or in part, because the product at issue was designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

14. Plaintiffs' claims are barred, in whole or in part, because the labels and information accompanying the products at issue were approved by the U.S. Food and Drug Administration or other appropriate regulatory agencies.

15. Plaintiffs' claims are barred, in whole or in part, by applicable products liability statutes or other law providing absolute or limited immunity or a disputable presumption of

immunity against liability for pharmaceutical products approved by the FDA. *See, e.g.*, N.J.S.A. §§ 2A:58C-4, -5.

16. Plaintiffs' claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards.

17. Plaintiffs' claims are preempted, in whole or in part, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing, and supply of Tasigna®.

18. Plaintiffs' claims are barred, in whole or in part, because plaintiffs' decedents' injuries, if any, were the result of conduct of plaintiffs, plaintiffs' decedent, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to decedent's pre-existing medical conditions.

19. If plaintiffs suffered injury or damages as alleged, which is denied, such injury or damage resulted from acts or omissions of persons or entities for which NPC is neither liable nor responsible or resulted from diseases and/or causes that are not related to or connected with any product sold, distributed, or manufactured by NPC. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of plaintiffs' alleged injury or damages.

20. Plaintiffs' claims are barred, in whole or in part, because plaintiffs' alleged injuries, if caused by Tasigna®, which is denied, were the result of plaintiffs' own idiosyncratic reactions.

21. Plaintiffs, or plaintiffs' decedent, failed to mitigate, which limits plaintiffs' damages, if any, in whole or in part.

22. Tassigna[®] was fit and proper for its intended purposes and the social utility of the drugs outweighed any possible risk inherent in the use of the products.

23. NPC has no legal relationship or privity with plaintiffs and owes no duty to plaintiffs by which liability could be attributed to it.

24. The claims of plaintiffs should be diminished in whole or in part in the amount paid to plaintiffs by any party or non-party with whom plaintiffs have settled or may settle.

25. Plaintiffs' claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

26. Notwithstanding the claims and contentions of plaintiffs, plaintiffs' decedent received all or substantially all of the benefit from the products that plaintiffs' decedent hoped and intended to receive, and, to that extent, any damages and/or restitution that plaintiffs might be entitled to recover from NPC must be correspondingly reduced.

27. Plaintiffs' causes of action are barred in whole or in part by plaintiffs' decedent's own contributory/comparative negligence.

28. Plaintiffs' recovery, if any, shall be reduced by those payments that plaintiffs receive from collateral sources.

29. If plaintiffs have been injured or damaged, no injury or damages being admitted, such injuries were not caused by an NPC product.

30. Plaintiffs' claims for punitive damages are barred because such an award would violate NPC's due process, equal protection and/or other rights under the United States

Constitution, the New Jersey Constitution, the Kentucky Constitution, the Ohio Constitution, and/or other applicable state constitutions.

31. Plaintiffs' claims for punitive damages are barred because plaintiffs have failed to allege conduct warranting imposition of punitive damages under New Jersey, Kentucky, Ohio, and/or other applicable state laws.

32. Plaintiffs' claim for punitive damages is preempted, in whole or in part, by applicable federal law.

33. To the extent that New Jersey law applies to plaintiffs' claims, plaintiffs are limited in the amount, if any, plaintiffs may recover for punitive damages under N.J.S.A. § 2A:15-5.9 *et seq.*

34. To the extent that New Jersey law applies to plaintiffs' claims, plaintiffs are barred from recovering punitive damages under N.J.S.A. § 2A:58C-5(c) because Tasigna[®] was subject to pre-market approval by the FDA, was approved by the FDA, and/or was generally recognized as safe and effective pursuant to regulations and conditions established by the FDA.

35. Punitive damages against NPC cannot be recovered based on alleged fraudulent representation to the FDA. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001); *see also* N.J.S.A. § 2A:58C-5(c); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004); *McDarby v. Merck & Co.*, 949 A.2d 223 (NJ Super. Ct. App. Div. 2008).

36. Plaintiffs' claims for punitive damages are barred in whole or in part because plaintiffs are not entitled to compensatory damages, no fault or other admissions being made.

37. Plaintiffs' claims are barred to the extent that plaintiffs seek relief under laws of states that do not govern plaintiffs' claims.

38. To the extent that New Jersey law applies, plaintiffs' claims are subsumed and/or barred by the New Jersey Products Liability Act, in whole or in part. *See, e.g., Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 54-55, 948 A.2d 587, 589 (2008); *In re Lead Paint Litig.*, 191 N.J. 405, 436-37, 924 A.2d 484, 503-04 (2007); *Brown ex rel. Brown v. Philip Morris, Inc.*, 228 F. Supp. 2d 506, 515-18 (D.N.J. 2002).

39. Plaintiffs' claims are barred because plaintiffs', or plaintiffs' decedent's, own negligence proximately caused and contributed to the injuries complained of and, therefore, the damages which might be recovered by plaintiffs in this action, if any, should be reduced in proportion to the plaintiffs', or plaintiffs' decedent's, own negligence.

40. NPC hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves its right to amend this Answer to assert such defenses.


JURY DEMAND

Defendant Novartis Pharmaceuticals Corporation demands a jury trial as to all issues so triable.

Dated: March 12, 2020

Respectfully submitted,

HARRIS BEACH PLLC

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*Attorneys for Defendant Novartis
Pharmaceuticals Corporation*

CERTIFICATE OF SERVICE

I certify that on this 12th day of March 2020, I electronically filed the foregoing Notice of Removal with the Clerk of the Court by using the CM/ECF system. I further certify that a true and correct copy of the Notice of Removal was served upon the following counsel via electronic mail and United States mail:

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